

The Healthcare Professions Act: revised decision-making frameworks for healthcare professions and reserved procedures executive summary



Background and request for advice

The Minister of Health, Welfare and Sport (VWS) has requested the Health Council of the Netherlands to advise on two regulations included in the Individual Healthcare Professions Act (in Dutch: 'Wet op de beroepen in de individuele gezondheidszorg'): the regulation of healthcare professions and the regulation of reserved procedures. Changes in healthcare and society have prompted an increasing number of requests for the regulation of healthcare professions in the Healthcare Professions Act. This increase has pointed to a number of challenges as to how decisions about these two regulations should be made. To future-proof the Healthcare Professions Act, the Health Council was asked to reassess the decision-making frameworks for the two regulations, as well as to advise on a comprehensive procedure for using the new frameworks in practice.

Decision-making should be in line with legislative intent

The request for advice has been handled by the Health Council's permanent committee on Ethics and Law. The committee assumed that there is no need to question the original legislative intent of the Healthcare Professions Act. What is needed, according to the committee, is more transparency and consistency in how decisions are made to regulate particular healthcare professions and reserved procedures.

To address this issue, the ethical and legal principles underlying the current decision-making criteria will need to be made explicit.

The committee asserts that decision-making – and therefore the criteria used – should be in line with the legislative intent of the Healthcare Professions Act, and should ultimately be based on foundational principles in health law and medical ethics.

According to the committee the following premises apply:

- The legislative intent of the Healthcare Professions Act is to promote

quality of healthcare and to protect the public against incompetent and negligent conduct by healthcare professions.

- Title protection ensures that only qualified individuals may use certain professional titles. The regulation of healthcare professions – by means of title protection – helps the public to distinguish healthcare professionals that meet the legal requirements from those that do not.
- The regulation of reserved procedures is prohibitive in nature. Procedures that pose unacceptable health risks to individual patients if performed by incompetent persons may only be performed by qualified and competent healthcare professionals.
- The regulation of healthcare professions and the regulation of reserved procedures are both government interventions that place limits on individual freedom of choice. This relates to two types of individual choice: the professional's freedom to provide healthcare, and the public's freedom to choose their healthcare provider. To avoid placing unjust limits on individual freedom, the government may regulate healthcare professions and procedures only if there is sufficient ground to do so (a default 'no, unless' approach).

A framework for the regulation of healthcare professions

The committee assessed that in principle the current criteria for decisions regarding the regulation of healthcare professions are in line with the regulation's legislative intent. Therefore, there is no need to draw up new criteria. It is, however, important to clarify the rationale behind the current

criteria to bolster the justification for regulating particular healthcare professions. Hereto, the committee considers it useful to order the current criteria in a different way.

The committee has established a decision-making framework with two distinct stages. The first stage consists of a number of preliminary criteria to establish whether or not the profession under review falls under the legislative scope of the particular regulation. After that, the second stage is designed to answer the question: to what extent is regulation of the given profession justifiable? Answering this question entails a normative evaluation that is based on the balancing of 4 ethical-legal principles: necessity, subsidiarity, effectiveness and proportionality. The committee proposes to use these principles as balancing criteria in stage two. In the application of the framework to actual cases – that is, whether a particular healthcare profession should be regulated – there is room for further specification of the criteria. This will provide the framework with the necessary flexibility to maintain its relevance in light of anticipated future developments in healthcare.

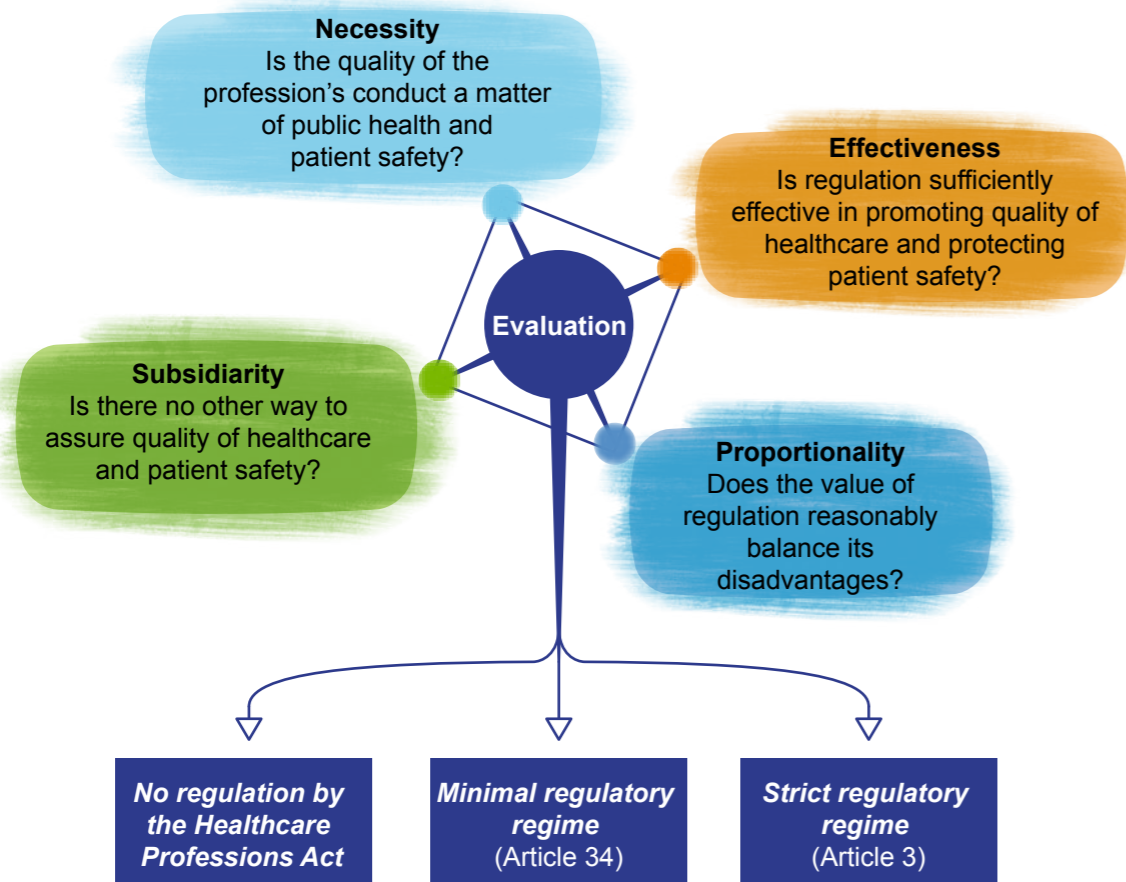
There are three possible outcomes to the evaluation: no regulation by the Healthcare Professions Act, a minimal regulatory regime (educational title protection) or a strict regulatory regime (professional title protection). Article 36a of the Healthcare Professions Act – which includes an experimental, temporary regime – has a different objective than the

Proposed decision-making framework for the regulation of healthcare professions

Does the profession fall under the legislative scope of the regulation of healthcare professions?

- ✓ It must be a **profession**.
- ✓ The profession must provide **individual healthcare**.
- ✓ The profession must provide **conventional healthcare**, as opposed to alternative medicine.
- ✓ There must be defined **professional standards** within the profession.
- ✓ The profession must have an accredited educational program with **assured quality in the Netherlands**.
- ✓ The field of professional expertise is **sufficiently distinctive**.

To what extent is regulation by the Healthcare Professions Act justifiable for this profession?



regulation of healthcare professions, i.e. promoting quality of healthcare and protecting patient safety. Therefore, the committee believes Article 36a should not be an outcome as part of this decision-making framework. The committee advises to no longer regulate professions under Article 36, and thus to abandon this regime altogether as its value is limited and does not outweigh the disadvantages.

Proposed decision-making framework for reserved procedures

Preliminary criteria

- ✓ Procedures **on, to or in the body**;
- ✓ Procedures for which there is a **direct causal relationship between their performance and the occurrence of harm**;
- ✓ **Singular procedures**, as opposed to complex or combined procedures;
- ✓ Procedures that are **specific and well-defined**.

Key criterion

Procedures that pose **unacceptable risks** to the health of patients if **performed by incompetent persons**.

A framework for reserved procedures

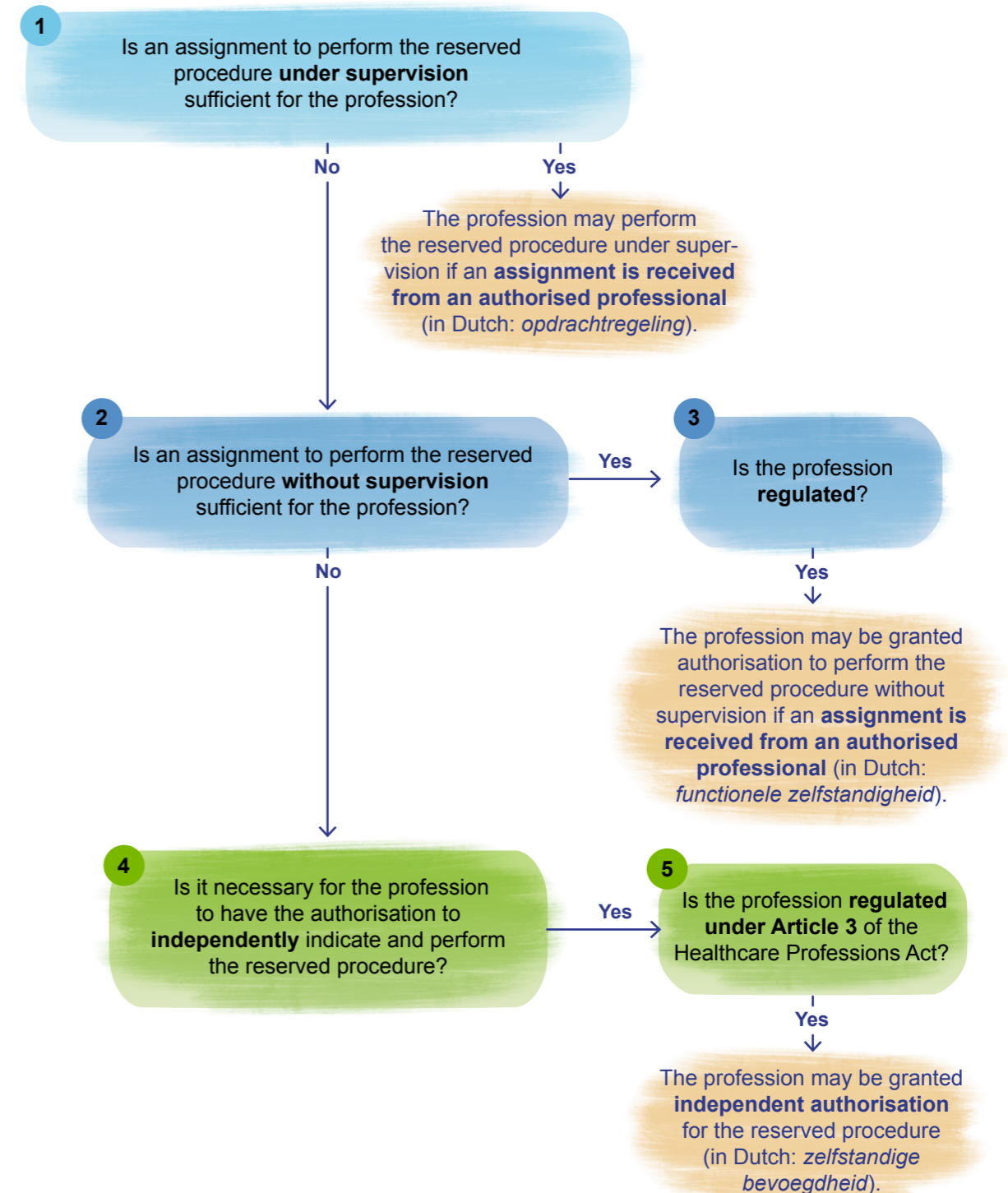
For the regulation of reserved procedures, the committee has established a decision-making framework largely based on the current criteria. Again, to support more consistent and transparent decisions the committee maintains that it is mostly about making the regulation's underlying principles explicit. As with professions, the first step of this framework is to determine whether a particular procedure would fall under

the legislative scope of the regulation, using a number of preliminary criteria. What follows is evaluating the procedure against the framework's key criterion, which is derived from the ethical-legal principle of non-maleficence (harm avoidance). The committee believes that the key criterion provides a compelling argument for government interference, and thus is in line with the default 'no, unless' approach: only regulate procedures when they pose an unacceptable risk of harm to patients.

The regulation of reserved procedures entails two types of decisions: in addition to decision-making about which procedures should be reserved, it should also be decided which healthcare professions should be authorised to perform specific reserved procedures. To that end, the committee created a decision-making tool.

Before investigating the possibility of granting a profession an authorisation to independently perform a particular reserved procedure, less far-reaching options should first be explored. The authorisation to perform reserved procedures also entails the authorisation to indicate whether and when to perform them, which requires the ability to assess the complexity and consequences of said procedures. An independently authorised professional may also assign other healthcare professionals to perform certain reserved procedures. In general, the default approach is that independent authorisations are not warranted nor needed for most healthcare professionals. When it comes to solely the execution of

Decision-making tool for granting authorisations regarding reserved procedures



reserved procedures, an assignment from an authorised professional may suffice.

At present, the committee has no indication that exempting specific elements of reserved procedures – under the assumption that they would pose less risk to patients and thus more professionals would be able to perform them – is either necessary or desirable. The committee anticipates more disadvantages than benefits from exemptions within the regulation, and does not see the need. Making more use of the legal possibilities to assign non-authorised individuals to perform reserved procedures seems more effective to this end.



Consistent application, justification and a clear procedure

With two new decision-making frameworks and one decision-making tool, the committee has intended to provide more clarity on the criteria used to make decisions relating to the Healthcare Professions Act. The criteria are derived from ethical-legal principles, and are intended to be balanced coherently.

The committee recommends that an independent review body advises the minister on all decisions relating to the regulation of healthcare professions and reserved procedures. The criteria in the frameworks outlined in this advisory report may be further interpreted and specified by this independent body. This will contribute to more consistent application

and thus a more robust justification of government interference.

The committee notes that the independent review body only provides advice and has no decision-making authority; decisions whether to regulate a healthcare profession or reserved procedure ultimately fall under the minister's responsibility.

The committee also recommends that the independent review body periodically reviews the list of regulated healthcare professions and the list of reserved procedures, for example once every five years.

To be able to anticipate technological and other future developments in the field of individual healthcare, the committee recommends that the list of reserved procedures be included in a general administrative order (in Dutch: 'algemene maatregel van bestuur', or AMvB). The list is now included in the Healthcare Professions Act itself and can only be amended with the approval of the Senate and House of Representatives. Incorporating the list of reserved procedures in a general administrative order would make it more accommodating to changes.

An often voiced concern regarding the Healthcare Professions Act is that the regulation of healthcare professions is used to serve purposes it was not intended for. For example, title protection allegedly has become desirable because it confers status and enhances a profession's appeal. According to the committee, there is nothing inherently wrong with

regulation serving additional interests. Provided the frameworks are applied consistently, those additional interests cannot, in themselves, justify legal regulation. Consequently, title protection is not the appropriate means to validate or acknowledge healthcare professionals.

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